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#26

JAN 21 1994

Robert S. Honor
Patent and Trademark Affairs
Sandoz Pharmaceuticals Corporation
59 Route 10
E. Hanover, NJ 07936

Re: Patent Term Extension
Application for
U.S. Patent No. 4,755,534

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,755,534 issued July 5, 1988, which claims the human drug product Lamisil Cream, is eligible for patent term extension under 35 USC § 156. The period of extension has been determined to be 543 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of May 18, 1993. Under 35 USC § 156(c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 (\text{Testing Phase}) + \text{Approval Phase} \\ &= 1/2 (1,095) + 547 \\ &= 1,095 \text{ days}\end{aligned}$$

Since the regulatory review period began July 9, 1983, before the patent issue date, only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period. The period of time from the start of the regulatory review period on July 9, 1983, up to the issuance of the patent on July 5, 1988, is 1,822 days. This period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: $2,917 - 1,822 = 1,095$ days. No determination of a lack of due diligence was made.

The 14 year exception of 35 USC § 156(c)(3) operates to limit the term of extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (December 30, 1992) when added to the period of extension calculated above (1,095 days) cannot exceed fourteen years. The period of extension is thus limited to December 30, 2006, by operation of 35 USC § 156(c)(3). Since the patent term of seventeen years (35 USC § 154) would expire on July 5, 2005, the period of extension is the number of days to extend the term of the patent from its expiration date to and including December 30, 2006, or 543 days.

The limitations of 35 USC § 156(g)(6) do not operate to further reduce the period of extension determined above.

U.S. Patent No. 4,755,534

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,755,534 a certificate of extension, under seal, for a period of 543 days.

Upon issuance of the certificate of extension the following information will be published in the Official Gazette:

U.S. Patent No.:	4,755,534
Granted:	July 5, 1988
Applicant:	Anton Stuetz
Owner of Record:	Sandoz Pharmaceuticals Corporation
Title:	PROPENYLAMINES, PHARMACEUTICAL COMPOSITIONS CONTAINING THEM AND THEIR USE AS PHARMACEUTICALS
Classification:	514/655
Product Trade Name:	Lamisil Cream
Term Extended:	543 days

C. E. Van Horn

Charles E. Van Horn
Patent Policy & Projects Administrator
Office of the Assistant Commissioner for Patents

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

RE: Lamisil Cream

FDA Docket No.: 93E - 0147